

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Ronald Reagan Building
International Trade Center
Horizon Ballroom
1300 13th Street, N.W.
Washington, D.C.

Thursday, March 18, 2004
10:06 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
ROBERT D. REISCHAUER, Ph.D., Vice Chair
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DAVID F. DURENBERGER
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JOSEPH P. NEWHOUSE, Ph.D.
CAROL RAPHAEL
ALICE ROSENBLATT
JOHN W. ROWE, M.D.
DAVID A. SMITH
RAY A. STOWERS, D.O.
MARY K. WAKEFIELD, Ph.D.
NICHOLAS J. WOLTER, M.D.

AGENDA ITEM:

Applying disease management to Medicare: Data analysis of fee-for-service enrollees; The Medicare Modernization Act and chronic care improvement - Rachel Schmidt, Chris Hogan (Direct Research LLC); Nancy Ray, Karen Milgate, Joan Sokolovsky

MR. HACKBARTH: Welcome, Chris. Next up on our agenda is a discussion of disease management and chronic care. Joining us is Chris Hogan from LLC Research. Rachel, are you going to set this up?

DR. SCHMIDT: Actually, it's Direct Research LLC. This is the first of two presentations on disease management and care coordination. The goal of this one is to lay out some context in which to consider the role that disease management might play in fee-for-service Medicare. The new Medicare Modernization Act calls for a chronic care improvement program. It's really a pilot program that will begin by this December and may be rolled out to serve a broader number of the fee-for-service population in three or four years.

Karen, Joan and Nancy will provide you with more of the specifics about that pilot program along with some of the things that we have learned from interviews we've conducted with physician groups, insurers, disease management companies, state officials and other experts. Our chapter in the June report is going to combine these two papers, the one we're about to give now and the one that Karen, Nancy, and Joan will give. But today we thought it would be easier for you to look over our data analysis first and then consider some of the policy issues within that context.

Two of the many goals for care coordination are improving quality of care and slowing the rate of growth in Medicare spending. Some analysts and policymakers have argued that the fee-for-service population is particularly well-suited for disease management because of its high prevalence of chronic conditions, the high concentration of spending that's associated particularly with hospital stays, and the perception that there's room for better coordination of care within the fee-for-service payment structure.

As practiced in commercial programs, disease management often involves targeting services such as beneficiary education and monitoring toward certain people based on their past patterns of care, the conditions they have, their prescription drug claims and self-reported health assessments. Chris Hogan and I are going to walk you through some data analysis based on the type of data that would be most readily available for disease management

services, or coordinating care in the fee-for-service population; that is Medicare claims data. We'll cover patterns of program spending and the prevalence of certain conditions within the fee-for-service population and try to answer some of the questions that you see on this slide.

Chris is not going to walk you through some of them methodology and caveats with this analysis.

DR. HOGAN: I'm briefly going to go through two slides on methods. The first slide is what you see in front of you. I'm just going to say, we're looking at a one in 1,000 sample of beneficiaries. Just to give a quick look and an easy way to get at modifying the analyses however you see fit. This slide just describes what we did. The more interesting slide is the caveats. I want to say, particularly relevant to disease management, a couple of strong caveats about the use of diagnosis information off claims to identify cohorts of beneficiaries.

The first thing you have to realize is, there's no standard way to do this. Every analyst decides which diagnoses you're going to count, which set of claims is going to be counted, how often you have to see a diagnosis in order to flag somebody's having a condition. The upshot is, the population that I call the CHF population may or may not match the population you'll see in some other piece of analysis. There's no standard way to do it, so there's some uncertainty. In addition, as you know, physicians may have some uncertainty in what they report on the bills themselves.

A second point that you need to keep in mind for evaluating a disease management or case management demo is that when you draw a population out of claims you're not looking at everyone who has the disease, you are looking at everyone who is being actively treated for that disease in the year. That means the cost you see in that baseline year when you draw that population are going to be higher, on average, than the cost you see the next year. Costs tend to regress toward the mean.

What this means for case management or disease management is that your target for evaluating whether or not the program has saved you any money is not, did costs go down, but did costs go further than I expected them to go down based on this regression to the mean that we know is going to happen? So it's not simple to evaluate whether or not a case management or disease management program has saved you money, because if I pulled the population from claims I'm looking at people being actively treated, and sure enough, next year the cost of that population will go down no matter what you do.

There are some other caveats here, particularly with regard to definitions of the institutionalized, ESRD,

and Medicaid that are not really relevant to much of the case management discussion so I'll turn it over to Rachel to discuss the results.

DR. SCHMIDT: So let's take a look at some of the statistics that Chris ran for us. I know it's not surprising to you that fee-for-service program spending is highly concentrated, but maybe the degree to which it is concentrated I found somewhat surprising. Our findings of concentration in spending are consistent with those of other researchers and they're also fairly stable from year-to-year.

We looked at the period 1996 to 2002. The top 1 percent of beneficiary ranked by fee-for-service program spending accounted for about 20 percent of total program spending in 2002 and had an average program spend of about \$9,600 per month which is about \$115,000 in that year. The top 5 percent of beneficiaries accounted for nearly half of program spending, and the top quartile or 25 percent made up nearly 90 percent of total spending. So this distribution of spending is obviously highly skewed.

Mean spending for the entire fee-for-service population was about \$500 a month in 2002. And the median, the point where half of the population had spending that was higher and half low was just \$92 per month. So the bottom three quartiles of people ranked by spending only accounted for about 12 percent of total program spending.

But you might next wonder whether high-cost beneficiaries remain high cost from year-to-year. That's an important consideration for thinking about how to identify who might benefit the most from better care coordination. In our data set one would look at these results and the glass could be half full or half empty.

This table shows one-year persistence in each year's beneficiary's ranking based on their spending. So the rows are showing you a person's rank in year one and the columns are showing their outcome in a subsequent year. If you look at the first couple of columns in you'll notice that some of our beneficiaries drop out of the data set between years because some die and some are simply lost from our sample: we're unable to match their data from year-to-year. These results reflect the average position of beneficiaries in our data set over any two years over the 1996 to 2002 period.

So now I'm going to take away some of this data just to make it easier to look at the most costly groups.

If you look at the circled value, this is showing that about half, 48 percent of the beneficiaries who were among the most expensive 25 percent in the first year were also among the most expensive 25 percent in the subsequent year, so that suggests a fair amount of persistence. But

among those people who were in the top quartile of spending in the first year, another 15 percent died, 1 percent were lost from our sample and the remaining 22 plus 11 plus four, which is 37 percent, fell into the lower three quartiles of spending in the subsequent year. So that's what Chris meant by saying there is a fair amount of regression toward the mean. A sizeable share of the high spenders are going to have much lower spending in the next year.

If your job was to predict who was going to be among the most expensive 25 percent in year two, about half of these people, the 28 plus 16 plus 8 percent there, were from among the bottom three quartiles in the previous year. If you remember, those bottom three quarters were only accounting for about 12 percent of spending in 2002. So that's telling you that some of the people who become very high spenders in year two are coming from relatively low amounts of spending.

DR. ROWE: Can I ask a question about that? You really should take the 15 percent who died out because we're not worried about what their expenditures are going to be in the second year, as we're looking at the efficacy of the program. So that then increases the proportion in these other quartiles by 15 percent or so because the size is now that 15 percent less. So your 48 becomes 55 and your 22 becomes 26 or something like that; is that right?

DR. SCHMIDT: Yes, that is right. We were trying to go for full disclosure here about what is happening to some of the people.

DR. ROWE: Regardless of how hard you manage disease, you hardly ever influence the expenses in the year after they die, despite the full disclosure aspect. So really you're up over 55 percent or so of the relevant population that could be managed, are in the first quartile. And if you look at the first and second together you're up by almost 80 percent; is that right?

DR. SCHMIDT: So you're a half-full kind of guy.

[Laughter.]

DR. ROWE: As an insurance guy, I'm aware that while there are no expenses in the year after death, there are also no premiums.

[Laughter.]

DR. SCHMIDT: Moving on. Disease management companies also use information about diagnoses from claims data to target enrollees or to stratify the services that different people receive and provide different intensities of care coordination. In the left-hand bars we show the prevalence of certain conditions, certainly not all conditions, as well as by certain characteristics of interest. In the right-hand bars we're showing you the share of fee-for-service program spending accounted for by

that group. Spending numbers contain all of the program costs for people who had those conditions including any of their comorbidities. People could fall within several of these categories at the same time. Clearly, in each of these groups they're accounting for a disproportionate share of spending.

So why did we pick these particular conditions and groups? Three of the conditions, CHF, COPD, and diabetes are considered threshold conditions for the chronic care improvement program in the Medicare Modernization Act. That means that these conditions are one basis by which people may be targeted for enrollment in that program. We also included ESRD because that population is one that might particularly benefit from better care coordination and we plan to devote some time and attention to that population as well as those with chronic kidney disease in our June chapter.

We also asked Chris to take a look at dementia because of its higher prevalence in the Medicare population. We think that is one unique aspect of the Medicare population that could make care coordination more challenging. There may be other factors as well.

The Commission has talked about other beneficiaries, such as those who are dually eligible for Medicare and Medicaid, those who are approaching the end of life, and people who are institutionalized as other populations of particular interest.

This table gives you a bit more detail about average Medicare program spending by the beneficiaries who have these conditions or characteristics that I just showed you. So you can see, for example, that fee-for-service enrollees who had a diagnosis in claims data of CHF spent an average of nearly \$1,900 per month in 2002, which is about 3.7 times the overall average of \$500 per month. The third column shows us that 41 percent of beneficiaries who had a CHF diagnosis in 2002 claims data fell into the top 10 percent of beneficiaries ranked by fee-for-service program spending. And since CHF is fairly prevalent, about 10 percent of fee-for-service enrollees have it, CHF patients made up a sizable share of everybody in the top 10 percent; 38 percent of those people.

By comparison, if you look midway down at ESRD, those costs per person are much more on average than CHF; nearly \$3,900 per month in 2002, or about eight times average program spending. This table shows you that 80 percent of the beneficiaries who had ESRD fell among the top 10 percent of people ranked by spending. But ESRD has much lower prevalence than CHF, only about 1 percent of fee-for-service enrollees have it, so those people with ESRD made up only about 6 percent of everybody who is among the top 10

percent.

You might be somewhat surprised comparing some of the groups on this slide. For examples, while beneficiaries with a diagnosis of diabetes certainly spent more than average, they're spending is less than twice the average versus some of the other factors that you see up on the screen that are much larger. Likewise, people who are dually eligible for Medicare and Medicaid had spending that was about 1.5 times the overall average.

I mentioned that some people point to the high prevalence of chronic conditions, particularly multiple chronic conditions, as a reason why the Medicare population might benefit particularly from better care coordination. Here we're showing the distribution of combinations of just the three threshold conditions that I mentioned were in the MMA, CHF, COPD and diabetes. So we're showing here that 74 percent of fee-for-service enrollees had none of those three conditions. But since this is based on claims data as Chris described, that is probably an underestimate of prevalence. Many of the 74 percent certainly had other types of chronic conditions.

We might see higher prevalence of these three conditions if we also were able to look at prescription drugs claims, which we did not for this analysis. Of the 26 percent who had one of these combinations, 20 percentage points are made up of people who had one condition, five percentage points of people who had two of these conditions, and one percentage point had all three conditions.

This slide is pointing out that the more conditions one has on average, that's associated with higher spending. That's reflecting the fact that people who have more conditions tend to require more complicated care, more types of specialists and providers and probably are at greater risk of needing a hospitalization. So for example, a person with a diagnosis of one of these three conditions had spending about 1.7 times the overall average, while someone who had all three was about 6.4 times more expensive than the average. Nearly two-thirds, or 63 percent of the beneficiaries with all three of these conditions fell among the top 10 percent of beneficiaries ranking by spending. But since those people are so few in number, they only made up about 6 percent of everybody who was among the top 10 percent.

It's kind of interesting to see that 37 percent of people who had none of those three conditions were among the top 10 percent. But again, they probably had other types of conditions that just were not included on this slide.

In your mailing materials there was also some discussion, some combinations of these conditions with dementia. I don't have a slide on that here but if you were

to compare pair-wise, people who have a condition and that condition plus dementia it does seem to add considerably towards their average spending, on the order of 1.5 to three times varying with that condition.

Finally, Chris took a look at each of our conditions and the populations of interest and the number of hospitalizations that they had and that's what this slide portrays. So in the far left-hand bar you can see that among the entire fee-for-service population 80 percent had no hospitalizations in a given year, 13 percent had one, and 7 percent had two or more. About 62 percent of beneficiaries who had ESRD, which is on the right-hand side, had one or more hospitalizations a year, which is probably not too surprising considering the complexity of that particular condition. But what I think we found was more surprising was that people with CHF had that same share as ESRD, about 62 percent had one or more hospitalizations.

ESRD patients were more likely to have repeated hospitalizations than CHF patients. Nevertheless, this information supports one thing that we heard repeatedly in interviews with the various experts that we spoke with. We heard over and over again that CHF was considered the low hanging fruit among different conditions for care coordination and disease management. In other words, if care coordination programs can educate patients and help them to monitor their conditions more closely then we might be able to avoid some expensive hospitalizations and improve the quality of their care.

DR. NELSON: Was the diagnosis applied during the index hospitalization? That is, congestive heart failure may be diagnosed initially as a result of a hospitalization which would tend to push that higher. Whereas, COPD may be diagnosed first in the office and a subsequent hospitalization would not necessarily trigger the diagnosis being applied.

DR. HOGAN: You're correct, that it may well have been -- the initial hospitalization during the year is where we picked up the CHF diagnosis. The last time I looked, one-third of Medicare fee-for-service hospitalizations have a diagnosis of CHF on them somewhere, so that probably explains -- that came out in the additional CHF payments to managed-care plans. So that may explain why the CHF hospitalization rate looks so high. We get one-third of hospitalizations in our population off the crack of the bat, and anyone else who is diagnosed on an outpatient basis shows up there as well.

DR. SCHMIDT: So let me finish up by summarizing some of what we've learned by looking at fee-for-service claims data. First, we found that program spending for beneficiaries is highly concentrated and high costs are

somewhat persistent. So about half of those who are among the top 25 percent of spending in one year were also among the top 25 percent in a subsequent year. But predicting who's going to be among the top 25 percent of spenders is a bit tricky because many of the people who are going to be among that top 25 percent are coming from the lower ranks of spending in the previous year.

It's common practice to also use diagnoses from claims to help determine who to enroll in care coordination programs or to tailor the sorts of services that they're going to receive. But Chris I think pointed out, or we told you in the mailing materials anyway, that diagnoses are not necessarily put consistently on claims data from year to year, so this certainly a limit or something you should bear in mind.

Finally, claims data are obviously going to be very important to CMS and to the organizations that are going to deliver care coordination for fee-for-service enrollees because they're going to need it to target enrollees and to tailor their services. But they may need to supplement claims data with other sorts of data, such as health assessments and prescription drug claims, if that becomes available. And timely access to Medicare claims information is going to be extremely important.

We'd be happy to take your questions and suggestions. Thank you.

DR. ROWE: A couple comments about this. I certainly agree with the view that predictive modeling and the selection of participants to be included is the important determinant in the financial and clinical outcome of disease management. I think that many of the disease management programs are commodities and they may be implemented to different degrees by different vendors, but the secret is selecting the right patients, and I think we need to emphasize that.

I think that a point that begs to be made in the chapter, which you mentioned in our comments but could be emphasized more, is the fact that with the Medicare Modernization Act we may start to get some information on medications. and that's going to dramatically improve the predictive modeling ability. Medicare currently doesn't have medication information. And it's important to understand that disease management in chronic heart failure is medication management. Many of these disease management programs are basically medication management programs. Certainly asthma is a great -- not so much in the elderly, but in the younger population it's all about medication management to keep the patients out of the emergency room.

So I would emphasize that, that the MMA provides us with an opportunity to be more effective in disease

management than we would have otherwise if we can capture the pharmaceutical information.

A third point is, it would be worth mentioning the distinction between disease management and these chronic diseases and chronic care, because if people aren't clinicians they're going to confuse the two. Managing a chronic disease is one thing; very important. The savings in these programs are avoiding acute complications of chronic diseases. It's the acute exacerbation of hypertension, heart disease, heart failure, the angina, the pulmonary edema, the stroke, those are the things we want to avoid. Those are acute illnesses that are treated in the hospital.

They're not chronic illnesses. They're the acute complications of chronic illness. As opposed to arthritis, which is a chronic disease that gets chronic care but which you're not necessarily looking for a target of an acute exacerbation. So these two things are a little bit different, as a clinical point.

It would be worthwhile knowing what the persistency is within disease categories, because while this global information you presented is helpful, there is no global patient. Every person is either a diabetic or a chronic heart failure patient or whatever, and those are the decisions that have to be made about the program.

The last point I would make is, I think it's important to say a few words about the role of the physician here, because we don't want to talk about the Medicare program coming in and somehow, in a way that's orthogonal to what the physician is trying to manage these patients. You read this chapter and where's the doctor? It's about Medicare and the patient. We want to talk about Medicare and the doctor and the patient, and helping the doctor use what is known about disease management for his or her patients who are Medicare beneficiaries.

I think that's really important because you will not get the patients to enroll or remain in the program unless the physicians are partners, I think.

DR. SCHMIDT: I think that's a very good point and I hope that you will find at the point when we integrate these two papers, we definitely in the second paper coming up try to emphasize that point and I hope we bear that.

MR. FEEZOR: Jack made more eloquently the two points that I was going to make. Is there any -- if we were able to include the pharmaceutical cost component would the arranging of the top five or the percent of money being spent be about the same, or is there any extrapolation on that?

DR. HOGAN: No. If you want to see it we can do it though. We can take the Medicare current beneficiary

survey, they have the drug costs there and if you want to see that we can do it. My guess is --

DR. NEWHOUSE: There's some data in the under-65 that show drug costs are more persistent than hospital and doctor costs, and there's no reason to think that wouldn't apply to the over-65. But the drug spend is probably a small enough part of the total it wouldn't importantly change the qualitative conclusions here.

DR. HOGAN: Yes, hospitalizations drive it.

MS. ROSENBLATT: Just a little bit more on what Jack said about finding the right people for these disease management programs. We found with the commercial population that a lot of the disease management involves patient self-management; people with heart disease not eating salt and things like that. So there's a compliance issue, and these are not going to be effective if you get the patients that aren't interested in being compliant or doing that kind of stuff.

I would think with the Medicare population there's an additional issue of who's capable of complying versus those who aren't; 65-year-olds probably can comply with some of this stuff, the 85 and 90-year-olds maybe would like to but just aren't able to. So I think there may be an issue there that we could explore more fully.

MS. RAPHAEL: I was just going to ask if you had any hypotheses about the dually eligibles, because you commented and I also was surprised that they are not as costly as one might have expected. I know from some work I've been doing on Medicaid high utilizers that among their most expensive encounters have to do with inpatient stays for psych, which we wouldn't at all capture here. But I just was wondering if you had any thoughts about that.

DR. SCHMIDT: One of our findings from some work that Chris had done was about half of the institutionalized are on Medicaid.

DR. HOGAN: Yes, a little more than half. You can watch them spend down to Medicaid once they're in the institution. So I think that most of the higher costs we see there are the costs of the institutionalized population being Medicaid. We should benchmark these numbers against others, but certainly CMS publishes statistics on the average cost by buy-in status and we can make sure we got it right, insofar as that's right.

DR. SCHMIDT: It does seem to be the case that the dually eligible are not a uniform population. There are some who are institutionalize and costs associated with that, and others who are less expensive. Let me put in a plug for the work that some colleagues are doing on the duals that you'll see later this afternoon where they're going to look at that in more detail.

DR. STOWERS: I was going to bring out the physician point, but another question, Chris, when you carry the data forward on the number of hospitalizations that involve congestive heart failure, is that there primary diagnosis?

DR. HOGAN: No, it's the economist looking at it; a dollar is a dollar. It was the total number of hospitalizations.

DR. STOWERS: They could come in with a fractured hip but had a previous diagnosis of congestive failure and it's still going to be a congestive failure admit then?

DR. HOGAN: No, I will still count them as having been admitted to the hospital and in my congestive heart failure bucket. Yes, they may have been admitted for a hip fracture but it's still one of their admissions.

DR. STOWERS: So getting to Jack's point about we're looking for acute exacerbations or preventing those within heart failure because of medication management or whatever, that may not be why they're back in the hospital. It could have been for -- so the fruit might not be quite as low hanging as we think.

DR. HOGAN: I would have no problem trying to flag the ones where the principal diagnosis was congestive heart failure or pneumonia.

DR. STOWERS: I think that's a huge issue because all of our practice, once they're labeled with congestive heart failure, that's in their history and physical when they come in. We manage the medications for that during the acute stay, even though they've had absolutely no exacerbation there and that's not the reason they're there. They could have come in for an elective, anything, and --

DR. NEWHOUSE: That should balance out between the non-CHF and the CHF patients.

DR. STOWERS: No, but your diabetes is carrying forward, your congestive failure is carrying forward. It may not be exacerbations of these at all is what I'm saying. I think it needs to be the primary reason they went in, that's what I'm trying to say.

DR. HOGAN: Right, I cheerfully break those out by principal reason for the admission. You'll find for the diabetics that almost nobody the principal reason is diabetes. But for CHF we'll see. I'll bet it's half, but we'll go look.

DR. STOWERS: It could be big. I just don't know what that --

DR. REISCHAUER: But Joe's point is the population you're comparing it to has the hip fractures, everything like that, in it already and what you're looking at is just the difference between the two.

DR. ROWE: The point is how much can be saved?

How many of the admissions that occur are potentially avoidable? And these unrelated ones are not unavoidable, right?

DR. REISCHAUER: No, but what you're looking at is the difference between the two and they are not in the difference between the two.

DR. NEWHOUSE: If the incidence of hip fracture is the same in the two groups, they difference out.

DR. ROWE: If what you're looking at is the difference. If what you're looking at is the number of admissions and you're assuming that they are avoidable, it may be that --

DR. STOWERS: We're saying the admissions are what's driving the cost up, trying to save acute exacerbations, that's not what this data is. It's just any admission that had that diagnosis.

MR. SMITH: Chris, just a quick caveat about your caveats. As I read the mail text I assumed that the failure of diagnosis persistency would raise the share of the most expensive cohort in the second year. Is that the right interpretation of that? So along with Jack's subtracting the folks who weren't around any longer, that number would still be higher because of the lack of coding persistence.

DR. HOGAN: If you want me to look at persistence by disease then I have to make an important choice as to when I'm going to flag somebody having a disease. Right now I do it one year at a time. If you had CHF in one year then you're a CHF patient. And if you didn't have it reported the next year you're not. If I'm going to look at persistence by disease I'll have to make some sort of decision rule about whether or not -- for example, if I have CHF in either year, should I now count you as a CHF patient? So I don't really know how to answer your question until I've gone back to look at the data to see how that will work out.

MR. HACKBARTH: Any others? Continuing now on the theme of chronic illness we're going to talk about the Medicare Modernization Act and chronic care improvement.

* MS. MILGATE: One of the most important challenges to the Medicare program is to find ways to better address the needs of beneficiaries with chronic conditions and ways to better coordinate care for all beneficiaries. The Commission stated its support for exploring these issues in past discussions.

In the private sector, an increasing number of purchasers and health plans are purchasing or developing disease management programs to address these concerns for their own enrollees, and many have also suggested these programs may be useful as a cost-saving tool. Recognizing this need, Congress established the foundation for a

voluntary chronic care improvement program in the fee-for-service part of Medicare in the Medicare Modernization Act. In this session and in the chapter in the June report we focus primarily on implementation issues coming from Section 721 in that act, but we'll also continue to evaluate the extent to which these goals are met more generally.

We ask you to consider whether this draft chapter addresses the issues you've identified in previous discussions and any additional issues that would be useful in the chapter.

Just a brief overview of what the provisions did in the legislation. The goals of the chronic care improvement program in the MMA are to improve the quality of chronic care for those with chronic conditions, improve the beneficiary satisfaction, and to achieve savings targets. The program is put in place in two phases. The first phase begins in December of 2004 with CMS contracting with contractors who will then take on responsibility for care management for particular populations. These contracts will be for three years and the program must overall be budget neutral.

CMS will issue a solicitation for bids in the next couple of months. The contractors' fees will be at risk. To move into phase two of the program, the individual programs must meet savings targets as well as quality goals, and overall the program will also need to show itself as budget neutral.

This slide just illustrates the implementation issues that we've identified and that we'll go through on this presentation. I'm not going to go through each of the questions but that's how the rest of the presentation will be organized.

The first issue, who will receive chronic care improvement services. First of all it's important to note that not every beneficiary is eligible for this particular service. The legislation allows CMS to determine how to define the regions where this will be available as well as to actually decide how to target the initial population; the key issue that you've identified in the previous discussion. In the legislation, the threshold conditions I noted are congestive heart failure, chronic obstructive pulmonary disease, diabetes, and then there is an other category which could be used if they decide there's another type of chronic condition to target as well. The legislation states that beneficiaries who will be eligible for this service will need to have one or more of those conditions.

Then there is also a question about what level of severity will be included in the target populations, and that's a lot of the discussion you've just had and Rachel showed data on how that's a very difficult issue to address

because many folks will be in the high severity level in one year and then move down to a lower category naturally without any intervention necessarily. And there are others who are currently at low risk who will move into a high-risk population. So that's one issue that will be a difficult one, both for CMS as well as the contractors.

The other question though that we take is important more broadly is whether this method of identifying those that would need these services would actually be able to identify a broad group of categories of beneficiaries who might need them. For example, those with chronic kidney disease, dually eligible, or those who at the end of their life and may need some care coordination for end-of-life care may be identified through the conditions that we have just noted, the threshold conditions, but in fact some of them may be left out and there may be some concern over whether they would actually be able to get the services they need given they aren't necessarily -- their CHF might not be their most important problem, for example.

The other category of people we think we might not be targeted as well as they otherwise could have been would be those who were at low risk, but at risk for these conditions, such as those with hypertension or high cholesterol.

So there's two levels of targeting. One is done by CMS and then the second level noted on the second bullet there is that contractors will also be able to decide what types of interventions to give to certain people. So what we were told in our interviews with a variety of different organizations that do disease management is that they, in addition to using claims data to target those that are high severity or high risk for some of these diseases, is then tailor the interventions based on health assessments and then more intense predictive modeling. So that, for example, a diabetic who has fairly controlled levels of glucose wouldn't necessarily have the same level of services as someone who has an uncontrolled level.

DR. SOKOLOVSKY: Another important issue, and it's already been identified in the earlier session is who will provide chronic care services under the act? The MMA states that these programs can be provided by physician group practices, disease management organizations, insurers, and integrated delivery systems. This we think is appropriate because there is no single model for the provision of chronic care. This is particularly true in the case of physician participation in the program. We saw a lot of models out there.

Programs range from those that are run by or for physicians to those where most or all communication between disease management organizations and physician is mediated

through the patient.

Physician-centered approaches include the primary care case management program in North Carolina Medicaid that we had a presentation on in our October meeting. Additionally, some physician multi-specialty group practices, and one example is the Geisinger system in Pennsylvania, have created disease management programs for management of their patients with chronic conditions. These programs employ nurses to handle patient education and care coordination, freeing physicians for more time to practice medicine, as they say.

Commercial disease management programs also have a wide range of relationships with physicians, but tend to focus more on patient self-management of their condition. Nurses provide patient education and monitoring services, but they also work with physicians in many different ways. All the protocols that are used by these organizations are developed by physicians. Some of the programs, but not all, use physicians to help identify patients who need the services and encourage patients to enroll. All of the programs provide data on their patients to physicians, and some provide additional data so that physicians can benchmark themselves against their colleagues.

Another question is what services will be provided. The MMA gives a very general list of services. It requires contractors to develop care management plans for each participant and these care management plans are meant to be tailored to the individual needs of the participant based on their levels of risk. The program must screen for additional chronic conditions and contractors must have enough information technology capacity to do predictive modeling, create protocols for nurse call centers, and evaluate the impact of their programs on an ongoing basis.

But specific interventions are not mandated. The law assumes that the programs will provide some services that are now covered under the Medicare program. For example, it says that programs should provide at-home monitoring technologies to beneficiaries if appropriate.

One service that's typically not provided by current disease management programs is case management. From what we heard in our interviews, disease management organizations typically refer their highest risk cases to either Medicaid or insurers' case management programs. Case management would be a particularly important service for the Medicare population because of the greater likelihood of their multiple comorbidities, and also because of their greater frailty level. Since Medicare doesn't have case management services, contractors will need to develop the capacity to furnish these services.

Another issue that is somewhat addressed in the

law but not in any great detail is how payment will be set. The law says that contractors will be paid on a per-member per-month basis but is not at all specific on what that will be. The contractors will bid to provide the service and CMS will then negotiate with the bidders based on the services they propose to provide and the population that they propose to provide them to.

Bids will take into account the services, and additionally, contractors have to take performance risk. That means that the fees that are paid to the organization by Medicare will be withheld if the programs do not meet their contracted goals. But they will not be responsible for any additional medical costs.

One aspect of the law that we're looking into is, I said at the beginning that it's meant to be available for many different models, but there are some aspects of the law that may make it difficult for group practices to participate. This is especially true because of the size of the areas in which the programs must be based. They must be based in an area where there are at least 10,000 beneficiaries with the targeted condition who are available to be a control group. And in aggregate the program must be conducted in areas where at least 10 percent of the Medicare beneficiary population lives.

Another important issue, while the statute gives chronic care improvement organizations considerable flexibility, CMS has ongoing responsibilities that will significantly affect whether the program succeeds or fails. First, current organizations require timely data to determine appropriate levels of intervention for enrollees, to reevaluate the risk levels of their population, and assess the effectiveness of what it is that they're doing. CMS will have to supply claims data to contractors at least quarterly and many of our interviewees said that monthly would be preferable.

Another issue which also has come up earlier is the issue of dual eligibles. Half of all states have Medicaid disease management programs and CMS is encouraging more of them to start these programs. But there are few mechanisms to coordinate care or share data between Medicare and Medicaid. Coordination is necessary to prevent redundant efforts. Also, if the data from both programs were available, targeting and care management would be much improved, and the beneficiaries in both programs would benefit.

Lastly, the MMA includes a number of other programs for chronic care improvement. All the new drug programs are required to establish drug therapy management programs for beneficiaries with multiple chronic conditions. Additionally, CMS is currently negotiating in its eighth

scope of work for the quality improvement organizations to address care for beneficiaries with multiple chronic diseases. In neither case is it clear how coordination between the drug plans and the QIOs and these new chronic care improvement programs would work.

MS. RAY: Another issue we considered is that most beneficiaries suffer from multiple chronic conditions as already pointed out to you by Rachel and Chris. Overall, about 70 percent of beneficiaries suffer from two or more conditions and 20 percent suffer from five or more conditions. Contractors will need to pay particular attention to conditions whose prevalence increases dramatically with age.

We specifically mentioned dementia and frailty as examples of those conditions. From our analysis, we learned that 5 percent of beneficiaries suffer from dementia. That probably is an underestimate because it is derived from the claims data. From MCBS we know that 15 percent of all beneficiaries have three to six activities of daily living impairments. Just picking up on Joan's point, of concern is that some contractors have limited experience in dealing with dementia and frailty in their commercial populations, and when they do have these patients they are often referred to case managers.

An issue related to the fact that many beneficiaries have multiple conditions is the use of clinical guidelines. Most current disease management contractors base their intervention on evidence-based guidelines. The concern raised by interviewees is that most clinical guidelines are typically developed for a single chronic disease and may be of limited help for patients with many comorbidities. In that instance, a physician who knows the history of a patient may have a greater capacity to tailor a care management plan to fit the needs of the individual.

I'd like to just now briefly raise two areas previously mentioned by the Commission as areas where care coordination has potential. The first is end-of-life care. To the extent that beneficiaries can be identified prospectively they may benefit from care coordination. The MMA does require that contractors' care plans include information about hospice and end-of-life care. Many of our interviewees agreed upon the need for care coordination for those near the end-of-life but that most programs were not yet effective in providing services for this population.

The second group I'd like to briefly touch upon are those with chronic kidney disease. Here the MMA does not include chronic kidney diseases as either a threshold condition or as a condition that should be somehow considered in the care management plan. The concern here is

that contractors may not address the needs of CKD patients or dialysis patients in particular because they represent only 1 percent of all Medicare beneficiaries. However, as Rachel pointed out, they account for about 6 percent of all spending. Dialysis patients could benefit from care coordination because they do suffer from multiple chronic conditions.

Next month at the April meeting we will be presenting you additional information about patients with chronic kidney disease, their spending before and after dialysis, and the potential benefit for screening for chronic kidney disease and providing interventions to CKD beneficiaries before they require dialysis.

The last issue we'd like to talk with you about is evaluation. Each program is required to be evaluated. The law requires that, and the law is specific as to requiring an assess on the quality improvement measures, particularly adherence to evidence-based guidelines and rehospitalization rates, and beneficiary and provider satisfaction, health outcomes, financial outcomes, including any cost savings.

As already touched upon by Karen, to expand in phase two a program's evaluation must show that the program improved the clinical quality of care, improved beneficiary satisfaction, and achieved savings targets. Your briefing materials raise five issues that CMS will need to address when thinking about how to evaluate each program.

First, the law requires the selection of a control group so that Medicare can assess the effectiveness of each chronic care improvement program. But the law does not address who is required to collect outcomes data like beneficiary satisfaction that's not available from the claims data, about the control population. That is, should it be CMS, the contractor's responsibility, or is it the independent evaluator's responsibility to collect that data?

The second and third bullet points are related. The law does not require standardized measures or a standardized approach to evaluate each program. If there is no standardization, the concern here is that it will be difficult to determine which programs are more effective than others. In addition, the threshold for expanding into phase two could vary from contractor to contractor.

The implementation of the Part D prescription drug benefit during the three-year study period could affect the analysis of a program's financial outcomes if, for example, controls are less likely to enroll than program participants.

The last evaluation issue I'd like to raise concerns the law's budget neutrality provision. That is, the aggregate sum of Medicare program payments for beneficiaries participating in the program and funds paid to

the contractor cannot exceed estimated payments that would have been made for participants in the absence of the program. It remains to be seen how the Secretary will structure savings targets for individual programs to ensure the overall budget neutrality.

Also, it remains to be seen what happens if individual programs achieve their goals but overall Section 721 is not budget neutral.

At this point we have completed our presentation and we'd be happy to take questions and hear additional issues.

DR. WAKEFIELD: I want to see if I understand this correctly. Would it be your case that the way this is structured that it's going to result in some pretty significant exclusion of rural populations, given an N of 10,000 and a control group and high numbers actually enrolled in the program? So what's your take about how accessible this will be for rural providers and populations?

DR. SOKOLOVSKY: In some way it might be the opposite because the regions will have to be very large and therefore one would think that they would go beyond any particular metropolitan area.

DR. WAKEFIELD: I'm thinking about a physician group, for example, and I would say the physician group based in my hometown of Grand Forks, North Dakota might have to service the entire state to get the numbers with a particular disease to be able to qualify to participate in this program.

DR. SOKOLOVSKY: I think that that is an issue with physician group practices and I tried to raise that because I think in general most of them may have quite a bit of trouble meeting that requirement.

DR. WAKEFIELD: If this appears in the June report I just hope that that would be pretty explicit. You can start to connect the dots as you're reading through the text but it's not clear. So where you see it playing an advantageous way, that would be helpful to see. I did not quite get there, but that would be helpful then if that's the case. I see the disadvantages and I think that where we can highlight those -- I mean, it just almost struck me as wholesale exclusion of some areas.

I actually have one other comment, and the comment is later on in a subsequent session we'll be talking about information technology applications with a discussion about the role of the federal government in terms of encouraging application of IT. If there's anything more you can tell us here about the use of IT with chronic care as it's embedded in these kinds of programs, I think that would be helpful, at least for informing my thinking about its application and the discussion that comes in the IT chapter. In other

words, how important is it, if you can get a sense of that at all. One of you mentioned it in passing in your comments, but it seems to me that if I had a better sense of how fundamental it was to this set of programs then that might help inform my thinking about recommendations and ideas that we'll have regarding the role of the federal government in encouraging the IT applications or not within the Medicare program. So if you could make those linkages in some fashion that would be useful.

MR. MULLER: I'd like to tie these two presentations together and especially three themes that arose from that, and then ask a question about it. First is the fact that 5 percent of the most expensive beneficiaries cost about \$60,000 to \$100,000 a year. I think that's what was shown in Chris' table. A lot of it does come, as Jack noted, from when patients with a lot of comorbidities, a lot of underlying disease have in fact acute episodes.

Second, the question of how well we can identify and target those people, identify them in any kind of way in advance.

Then third is, what kind of interventions could we in fact put into place that would help us both improve the quality of the care, the quality of life, and also avoid some of the costs? Because it strikes me, if it's costing us -- there will obviously always be a top 5 percent of cost, but in fact there are beneficiaries who we could help avoid some of these acute conditions and if we knew how to target them and knew how to do the interventions, at \$60,000 to \$100,000 per patient a year you could think about spending an awful lot of money. You almost could have a daily check in with them with a nurse or something like, absent privacy and other kind of concerns, but just as a way of thinking about it. You would think about a lot of interventions you'd want to think about both in terms of keeping them out of those life-compromising situations.

So to what extent are we going to be able to, as part of these analyses and these programs, look at those kind of issues of whether in fact we can target those patients better, because in some ways a lot of our programs are thinking about millions and millions of beneficiaries. But in some ways if we could target a very small subset of beneficiaries and understand what kind of interventions we could make that would make a difference by keeping them out of these acute conditions, that strikes me that would be a major advance in their quality of life and also obviously have big cost savings implications. So to what extent do you think we will be able to find those kind of things out through these analyses and these studies?

MS. MILGATE: I don't know if we can really answer the extent to which. I think you put your finger on the two

real critical questions, which is how possible will it be to actually target these people? Number two is, will the programs that are contracting with Medicare be able to deliver the kinds of services that those folks in particular would need.

Clearly, those are some folks that are using a lot of services and there are a lot of physicians and a lot of different facilities involved so some real serious case management is what it would call for. But I don't know if either one of you want to comment on the extent to which we could actually identify them.

MR. MULLER: In some ways, whether it's Mary's point about the populations in North Dakota or other such issues about how one changes the whole system, in some ways it may be easier in a complex world to figure out how to target individuals who need this kind of help more so than to try to change physician practice patterns in America or a payment system. These other things are very hard to do. But if in fact we could -- for many of these people, since a lot of them -- I don't know whether the top 1 percent -- I know there are 15 percent who die so the top quartile, what the rate would be in the top 5 percent and so forth, but obviously is we could maintain and continue a quality of life for them rather than having these acute episodes, that could be a major advantage there as well.

DR. MILLER: Just to respond, when you were saying we, did you mean the Commission's work or the work related to this program?

MR. MULLER: The latter.

DR. MILLER: Okay, because that makes me much more comfortable. I think we'll be able to do broad data analysis and talk about potential populations. I think one of the key evaluation issues will be when you grind down into these programs, how do these programs actually go about -- because a lot of them will start with administrative data but then gather additional information through their contact, phone calls and that kind of thing. That helps them actually do the targeting. Some of the evaluation I think has got to get to which of those interventions really get to the target and then actually have an effect. So I think your point is taken. I was a little worried that you were wondering whether we were going to be able to get to that point, and I don't think so.

MS. RAPHAEL: I'm not entirely clear who is going to do the targeting. Is CMS who's going to do the targeting, or is the contractor who's going to do the targeting?

MS. MILGATE: I maybe wasn't clear. There's really two levels. The first level, CMS is given the ability in the legislation to decide what actual population

is eligible. And the legislation's guidance is that the beneficiaries have to have one or more of these conditions. It's CHF, COPD, diabetes and other. Within that though there are some issues of what level of severity, where the beneficiaries may live, and then in particular regions, as Nancy noted, there's also a control group. So those folks might actually have some of those conditions like their neighbor but not necessarily be targeted good for interventions.

But then when the contractor actually takes responsibility for managing the care of the particular population that's targeted, what I was saying is what we generally heard from our interviewees, even at that level there's another level of targeted that happens to basically determine what types of interventions to give to different people in your population. So those with a diabetes would get different interventions, clearly, than those with CHF.

But actually, one thing we didn't emphasize is that once those beneficiaries are targeted through their threshold conditions, the contractors are responsible really for their overall care. So they don't just manage presumably their CHF. They're supposed to look more broadly at what else might be useful to manage for that particular beneficiary. So then there would be different levels of intervention depending upon the level of severity, the other types of conditions, some of the information they may gather from personal visits with the family or phone calls with the beneficiaries. Some of them have told us, for example, they may, over a period of time, pick up some dementia on the part of the beneficiary and then maybe target their interventions a little bit differently.

Does that answer your question?

MS. RAPHAEL: We've always come back and worried about selection issues and I'm wondering to what extent, if I'm a contractor, can I then just take one slice of this very broad population, one or more chronic conditions, and just target people who have diabetes and try not to get people who have CHF or COPD or dementia?

MS. MILGATE: It depends a little bit on what CMS does. If a contractor has to have people in its population that are of all those kind or only one kind, I don't think we know for sure how that will happen. But it does leave that flexibility. I would suggest that if they had those three conditions they maybe could target what they thought was going to be the most -- the condition that would be easiest to improve or else have more ability to keep more people out of the hospital, for example.

DR. SOKOLOVSKY: Can I take a shot at this? The RFP will go out and contractors will bid for a particular population in a particular area. But it is CMS who will not

only target that population but make the initial contacts and decide who's going to be enrolled in the program. Then CMS will give to the contractor all the people that they are responsible for, and they will be taking performance risk for all those people whether they intervene with them or not. So if you try to avoid the people that would be more expensive, in fact it will cost you more.

DR. ROWE: The contractor is responsible for the care of the patient? CMS determines this?

MR. HACKBARTH: Let me pursue it because I'm still trying to envision exactly how these work. So will the contractors in effect have an exclusive market area where they will have responsibility for a set of Medicare beneficiaries? That they get the list from CMS so they will be the contractor in that particular geography for this list of beneficiaries?

DR. SOKOLOVSKY: The law isn't exactly clear about it but we are assuming, especially given the requirement that all in all these programs have to be spread out so at least 10 percent of the population --

MR. HACKBARTH: Because you could eliminate one set of selection issues in your evaluation process if you say that it's an exclusive contract to deal with this set of beneficiaries with chronic conditions, A, and C.

Let me just play this out for a second. Now CMS in order to have randomization for purposes of evaluation has said that these beneficiaries are eligible and these are not. It's the responsibility of the organization to then do the outreach to the individual beneficiaries? But the individual beneficiary has a choice on whether to participate or not?

DR. SOKOLOVSKY: Yes.

MR. HACKBARTH: So another type of selection might be introduced at that step depending on the nature of the outreach.

DR. SOKOLOVSKY: Yes and no, because CMS will have made the first contact and CMS will give to the contractor the list of all the people that they are responsible for. So if the contractor attempted to, for some reason, to discourage some of the people they would still --

MR. HACKBARTH: They would still be calculated for purposes of the overall evaluation. If you discourage the more challenging patients then you would be stuck with their high cost at evaluation day.

Now what about getting to Jack's point about the role of physicians in this? If you're responsible for an entire area, that really biases the model towards an all-inclusive physician model, because if you discourage physician participation you're not going to be able to manage, influence the cost of beneficiaries who see those

physicians. So the basic model is an open network with regard to physicians?

DR. SOKOLOVSKY: If a physician group practice bids then they can be as closed as they want. But I do think there are things that would bias against that.

MR. HACKBARTH: If you're going to do, how can you possibly do well on the evaluation if you can't relate to the other patients that go to other physicians?

DR. MILLER: Can I say something about this? There may be different ways that it can happen, but just to try to get a fundamental understanding. You have an area and you have some entity that says, I will disease manage for this area. They may have very different models they may go -- they may go at it and say, the way we do disease management is we really have a heavy involvement with the patient, so we really talk to the patient about their care and we work through them. Another disease management group or entity may have a very physician-focused approach to it.

So in this instance we would say -- a lot of this is evolving so just in terms of exactly what's going to happen but this is the area. The entity would come in and overlay the fee-for-service setting in that area and then use its disease management tools to target and either work with the patient, work with the physician, work with both, whatever their particular intervention style is.

DR. ROWE: Most of these programs are telephonic programs with nurses and we need to understand what these programs are. They are telephonic programs with nurses using an ongoing updated database. So the nurse notices that a prescription was not refilled or whatever and calls--

DR. REISCHAUER: And they're going to get the information from the 30 drug plans that are available within that region on a timely basis? When I read this I wrote, unworkable, on the top. My question was going to be, is there a lot of interest out there in the industry about this, because you have the scale issue, you have the fees at risk, it's only three years long. You have the fact that it's \$100 million, which is chump change for what we're talking about. It struck me as a great expression of interest in something but then packaged in a kind of unworkable way.

MS. MILGATE: Can I just comment on that? I think all of that is true, but at least the disease management vendors we spoke with on the other side of it for them is in particular they believe that congestive heart failure, and they have worked some with diabetes, but because of the prevalence of congestive heart failure in the Medicare population and some of the other chronic conditions that in fact it represents a huge opportunity. But you're right, there are a lot of ways that it makes it a pretty difficult

job as well.

DR. ROWE: One way it might work, Bob, just to respond to you is, if you have a group of cardiologists who are doing a really good job and they have a lot of Medicare beneficiaries with CHF, which we should refer to, by the way, as chronic heart. That's what it stands for. Because not all chronic heart failure is congestive. Some isn't. So it's chronic heart failure. They have a bunch of patients with chronic heart failure. They may already have hired nurses, advanced practice nurses who are specialists in cardiovascular disease who are following up on patients, doing home visits, on the phone, checking the medications, doing a really good case management job which they're currently not getting paid for at all.

DR. REISCHAUER: So we pay them and make it budget neutral? Pay them to do what they're doing already?

DR. ROWE: That's a second question. I'm just responding to your question about is it worth it to anybody to do it? For those people who are really working in the patient's best interest, because the better the case management is, the fewer doctor visits there are, the fewer hospitalizations and the fewer Medicare claims these doctors submit, quite frankly. But they are doing a good job for their patients. Those physician groups would be benefitted by this, and probably would apply.

MS. RAY: I just would want to add another point. There's nothing in the law that explicitly says that phase two is budget neutral, and phase two can begin as early as, I believe, two years after the implementation of phase one.

MR. HACKBARTH: I have several people who have been patiently waiting.

DR. STOWERS: I just wanted to get back to this a little bit. We kind of leave the attitude through the entire chapter that, I think the statement is, Medicare currently does not provide case management service or chronic care services. I would contend on a daily basis millions of these patients with multiple of these diagnoses are receiving millions of Medicare dollars through their primary care physicians' offices and practices to be getting this very service. I haven't heard any service mentioned today that our practice plan doesn't provide for these patients. The point is made, it's not being paid for in a lot of cases. It's just coming out of the base budget of the practice. Maybe that's an answer for the rural areas that don't meet the requirement for the 10,000 or whatever, that we could have some other way of rewarding those, but it that's another story.

Another thing, we've learned the very hard way with these kind of services is that unless they go through the physician's office and involve the physician -- we said

in our access chapter that 92 percent or whatever had a primary care provider and they were happy with that, and 80 percent of the people entering the system here are coming through a primary care provider. Yet when we get to this chapter we just leave all of that out, and that's what the primary care providers do.

But my one last point is that, again what we've learned is that unless you are going through that physician and they're just receiving the phone call or the letter or whatever and you have this content patient with their family physician or their primary care provider, it's kind of like water off a duck's back. They may bring it into you and they may show it to you, but they're happy where they are, they're happy with their doc, and that's what our own data shows. So I think somehow we've got to bring that around, that this is an all-new service and it's an add-on, it's a help or whatever to what's already going on out there. And noted it needs to be done a lot better.

MS. RAY: I just want to ask for some clarification though. Do you think it's an issue with the recruitment of patients, the fact that physicians initially are not going to -- it's CMS being --

DR. STOWERS: I can tell you on the plans that we did, and currently another one just tried it in our practice, those that did not go through the physician that were just starting to contact a group of patients out there had almost no response. It was just very, very poor. I have read stuff on that that -- do you agree, Jack?

DR. ROWE: Yes. Patients get bombarded with so much stuff, many of them are not going to be able to differentiate this. They're just going to think it's some other vendor out after them and they're going to do what their doctor recommends.

DR. STOWERS: But when we tell them, they're right, this is something you need to do, you need to go get your eyes checked once a year, then it happens. So we need to identify those that aren't getting care and help them come into the system and that kind of thing. Don't get me wrong, there is a lot of help to be done out there. But if it's done independently, if somebody just gets assigned a big bunch of people and they're going to start making phone calls and all of that and don't incorporate the current health care system --

MR. HACKBARTH: But I think what that means is that the smart organization will go through physicians and try to involve them in the process, and the ones who don't do that, if you're right, will just fail and won't succeed. Presumably, to the extent that we have contestants, if you will, who are experienced in the private sector, they're well aware of that lesson already and they're not new to the

enterprise when they come to Medicare.

MS. ROSENBLATT: I think one of the things that MedPAC could do to help with this is do some, analysis and let me describe the analysis. Wellpoint has tried to quantify the impact of disease management programs, and as you so correctly state in the text there's a lot of that quantification that's been done that it's not really quantifying that. It's quantifying regression to the mean and other things like that, and I think you made a good point about that. So we have thought about using a control group and have tried to use a control group to quantify it.

What has happened in an attempt to do that is, first of all, when you look at a particular disease category, like look at diabetes, look at diabetes within a particular area, you're going to find that the range of annual cost is very large. You might have some people with diabetes spending \$100 and others spending \$100,000. So then you get to, with that wide range, in order to prove that there's a meaningful, statistically significant difference between the control group and the group where you're using disease management, you need a very population.

That's an analysis you could do, pick what's the statistically significant difference and what does that mean your population needs to be and I think you'd get some very interesting results. Now particularly if you think about it in connection with Mary's point about the rural areas, or even, I think within a large metropolitan area you're going to have problems.

DR. NELSON: I don't worry so much about these entities when they incorporate their activities within the existing care system. But there will be some areas where they'll go in parallel as an alternative to the existing care system. Some of those won't make their performance risk targets and they're going to go belly about, and I worry about disruption of care. I worry about them leaving a whole bunch of beneficiaries confused. If the beneficiaries are lucky, whoever was taking care of them before will welcome them back, but there's going to be some disruption.

At least that seems to me to be a realistic possibility and I think that somewhere we ought to point out that to the degree that this is set up as an alternative to the existing care system it poses some risk, a disruption of care if they don't make it.

MS. MILGATE: It doesn't require actual building of networks, so people wouldn't change physicians for example.

DR. NELSON: No, but I can see one of my patients saying, I'm going to the diabetes disease management outfit now and they'll be taking care of my multiple chronic

illnesses, and that may be quite an expectation for a nurse to handle, for example. I know ideally they will reinforce and support the existing delivery system. But if there's an opportunity for entrepreneurs I'm not sure that they will necessarily integrate with the existing system.

DR. MILLER: I guess what I don't follow in the comment is, do you think that they're going to go and get their care there, or just that they're going to be having communication with -- when you said, I could see a patient saying, I'm going to go to my diabetes management growth, did you think that they were going there to get care?

DR. NELSON: I infer that they will be receiving advice and some of that advice might be with respect to their treatment protocols and the medications they're on and so forth. Is that inaccurate?

DR. MILLER: No, I think that's correct. But did you think that they were going to go to a different physician, I guess that was --

MR. HACKBARTH: What I thought he was referring to was educational groups. Not necessarily a different physician but there are educational programs that may involve going on to a different place.

DR. NELSON: And changing the treatment protocols, putting the patient on a whole new regimen and then disappearing. That's what I'm talking about.

MR. HACKBARTH: So even if it's not a physician there is engagement, ongoing relationships that could be disrupted I think is what Alan is saying.

DR. ROWE: For example, if they have a reason to prefer one type of cholesterol-lowering drug than another, they're going to be on the phone with the patient talking with the patient every week about the medications and they can say, you're on Lipitor but we think you should be on Pravachol or vice versa. Something like that would be a way in which they could influence the system, but the physician still has to write the prescription. So the physician is still in control with respect to that.

I don't feel the same concern Alan feels about what might happen but I may not be envisioning the kind of entrepreneur that may find a loophole.

MR. HACKBARTH: Let me just a comment to the broader audience. What I think is going on here is we're trying to envision what this is exactly and have questions about how it will work and how it's connected to the underlying delivery system and insurance program, and it's not all that easy to imagine it. So I caution people against interpreting all of the question as being negative on the idea of disease management for the Medicare population.

To the extent that we've discussed it in the past

I think the commissioners have generally been very positive about the concept, but now we're trying to come to grips with how it might be operationalized and it's complicated and raises lots of challenging questions.

DR. WOLTER: My comment is kind of on that point because I'm still not sure exactly what is possible in the design of this, and that would affect a lot of how it unfolds. For example, if 10 percent of beneficiaries have to be in one region, that's either a highly dense urban area or a very, very large geographic area.

MS. MILGATE: It's 10 percent overall have to be in the program, but then it's 10,000 within a region.

DR. WOLTER: It says 10 percent here.

DR. REISCHAUER: They don't have to be enrolled. They have to be in the geographic area.

DR. WOLTER: It says will be offered in geographic areas where, in aggregate, at least 10 percent of all of Medicare beneficiaries live.

DR. REISCHAUER: But the capacity of the contractor that wins might not be such as to be able to serve all 10,000 if they --

DR. WOLTER: I'm getting to that point. But is the region envisioned to be in an area where at least 10 percent of all of Medicare beneficiaries live?

MS. MILGATE: All of the regions together have to add up to at least 10 percent.

DR. WOLTER: Then once the regions are defined, is it possible that the law as it's written would allow more than one contractor to be chosen to do disease management?

DR. SOKOLOVSKY: It's not really clear except for the fact that the contractor will bid for a threshold condition but then be responsible for all the other conditions. The idea of having two contractors in one region using a different threshold condition but contacting patients, perhaps the same patients and trying to manage them, one for their diabetes and one for CHF I think would leave it --

DR. WOLTER: That could complicate it. The reason I ask is that that would allow the potential that rural areas could have somebody involved. It could allow the potential that group practices could manage a smaller number of patients but still be involved in the program, and it would allow it to compare how group practices do compared to private vendors, this whole issue of how do you intersect with the providers. But the devil is in all those details in terms of what would be possible.

My last comment is just that we were one of 12 or 14 organizations chosen for a group practice demo by CMS and in many ways what we're working through with CMS on that demo is very similar to these issues, because we're trying

to look at how do patients get chosen, how do we compare them to a sample group, how do we look at the costs that would be in the group we manage versus that group, how does the incentive get created if we do something more efficiently than the sample group, and then what measures are going to be used to look at the quality on the quality side?

I will tell you, this has been very difficult, just this little small project with 12 -- this is to your point of being unworkable I think, Bob. It's been very, very hard to get to those details. I think CMS has had to struggle with it.

Also there's another issue that comes up that will, I think, be in play here and that's HIPAA and how patients are identified and screened and who has access to patient-identifiable records, and when happens and how do we deal with the regulatory side. There really are a lot of issues here that I'm not quite sure what our role is, but it has a lot of promise but it is hard to imagine some of these details.

DR. NEWHOUSE: Like Alice I want to make a comment about the evaluation, but it really is triggered by Jack and to some degree what Nick said. Suppose that we have some good guys out there who are doing a good job in disease management and they're not getting paid for it because they're not a covered service, but it is in fact effective. And that these are the people that come in and say, okay, pay us, we'll do it. And CMS looks at them and says, yes, it seems like you're doing a good job, we'll put you in the demonstration.

My problem is that these people won't show, presumptively, any reduction in their cost because they're already getting it. Then if one says, all right, so evaluate them against the bad guys, then you won't know if it's the disease management or the fact that these are just better doctors or better something or others.

So I'm not sure, given this process of selecting people, how it is evaluated in a way that sheds any light on the effectiveness of disease management.

DR. REISCHAUER: But you say this practice is doing the right thing now and has these ancillary services and all that, and that is presumably the difference between another group that doesn't have it.

DR. NEWHOUSE: But maybe it isn't. Maybe these are just better -- maybe these guys are using better -- there's better medication management here anyway because these are the cream of the crop of the doctors that are doing -- they're better cardiologists than the other guys.

DR. REISCHAUER: But you won't necessarily know that if a group that hasn't been doing the good things pops

up and says, I will do the good things. They might be better doctors as well.

DR. NEWHOUSE: Yes, but I still am stuck I think in evaluating. I don't know what to make of it.

MR. SMITH: I'll try to be quick. Actually my comment was the flip side of Joe's. But let me go back and make sure I understand your answer to Carol's original question. CMS is going to hand the contractor 10,000 lives.

MS. RAY: No, it's 10,000 controls. The law doesn't specify how many program participants. It specifies that there's 10,000 --

DR. REISCHAUER: It's going to hand them a geographic area in which there are 10,000 potential participants.

MR. SMITH: At least 20,000.

MS. RAY: Controls, so there is even more.

MR. SMITH: Joe asked the other half of the question I was going to ask. If Ray and Jack are right, and it seems to me they are, that there are good general practice docs out there doing this stuff, and their patients say, I don't need this, when CMS calls, they end up perhaps in the control growth. They're getting this good stuff from good docs who aren't getting paid for it. I think Joe is right, if they have been getting this good service they are likely to show less improvement than folks who haven't been. Somehow it seems to me the design issues here are really screwy. I'm back to Bob's unworkable comment. I had somewhat the same reaction as I read it.

Let's assume we have a thoughtful medical consumer who is being well treated and getting this sort of coordination and management and has got a nurse or a physician's assistant that she feels comfortable with, why on earth would she say yes when CMS calls?

DR. NELSON: To get home testing equipment, all kinds of stuff.

DR. REISCHAUER: But presumably we're in this because there aren't very many people in that fortunate circumstance. SO the impact might be biased downward but it's not going to be obliterated by that fact.

MR. SMITH: It makes the design issues very complex.

DR. ROWE: I think I'm on the wrong committee.

DR. REISCHAUER: Finally, a consensus has been reached.

[Laughter.]

DR. ROWE: I think I'm finding myself on a study design committee, and that's not the committee I'm supposed to be on. I think there are some issues here, but let's not talk ourselves out of a good thing. There's no way this could be a bad thing for Medicare beneficiaries. They need

it. There are a lot that aren't getting it, and I think we have to focus on that. We do have to understand that this is not a substitution but it has to be a supplement for the existing care system in such a way that we pay a fair price for the right services and we target the beneficiaries. We're raising some questions but I don't think we can answer them now.

DR. REISCHAUER: And the presentation made it clear that CMS has a lot of flexibility in the way it goes forward on this. So we shouldn't raise all the devils until they produce the detail.

DR. MILLER: The only thing I would say about all those last sets of comments, I think this is some of the places where we can make a contribution. So that rather than waiting to see the details on the evaluation, for example, we might raise some of these issues. I'm sure people at CMS are thinking about this too and can help provide some guidance. Then as we think through some of the other implementation issues we can talk about that. I think these are the kinds of questions we can actually help with.

MR. HACKBARTH: But I think Jack's comment is a good one to leave on. Again, I don't think that we are negative about this same idea. In fact to the extent that I have concerns about the evaluation I'd be worried that the results would be biased downward as a result of some of these issues.

Okay, good work. More on this later. Let's move ahead to what's next, and that's IT, I think.